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Dated: August 6, 2009

Signature: /David A. Gass #38,153/
(David A. Gass)

Docket No.: 31265/5868A
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Xin Lu et al.

Application No.: 10/582,316

Confirmation No.: 1608

Filed: February 20, 2007

Art Unit: 1642

For: TUMOUR SUPPRESSOR PROTEIN

Examiner: M. T. B. Davis

**APPLICATION FOR PATENT TERM
ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

The Applicant/Patentee requests that the U.S. Patent and Trademark Office (PTO) reconsider its calculation of Patent Term Adjustment (PTA) for the above-referenced application. The exact PTA depends on the eventual issue date, but will be in excess of the nine days of PTA calculated by the PTO in the Notice of Allowance, due to the PTO's failure to issue the patent within three years of pendency.

I. INTRODUCTION

"A Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than a three year application pendency.

II. THE APPLICANTS DO NOT CONTEST THE PTO'S CALCULATION OF "A DELAY" FOR THE PRESENT APPLICATION

Solely for purposes of this request, Applicant does not contest the PTO's calculation of "A Delay" of 33 days due to failure to issue a first action (restriction requirement) until May 23, 2008, which is 33 days in excess of 14 months from the §371 completion date of February 20, 2007 (see PTO calculation attached hereto).

III. THE PTO MISCALCULATED "B DELAY" TO THE DETRIMENT OF THE PATENTEE

The PTO did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). The PTO accorded no PTA for "B Delay." To arrive at this conclusion, the PTO may have measured application pendency from February 20, 2007, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, the governing statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application -- not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371, if such date occurred later. As explained in detail below, the relevant 30 month date is June 10, 2006.

A. Authorities that define "B Delay"

The statute provides, in relevant part, that the term of a patent shall be extended if the PTO fails to issue a patent within three years after the "actual filing date" of the application:

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.
35 U.S.C. § 154(b)(1)(B). (emphasis added)

The PTO's governing rule explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a

national stage application begins if the PTO fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. 371(b) or (f)."¹

(b) *Failure to issue a patent within three years of the actual filing date of the application*. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... .

37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences":

(b) Subject to subsection (1) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. (emphasis added)

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with.

Section 371(f) relates to international applications for which an applicant files an express request for early processing, not applicable to this case. Absent such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from the priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b). See also MPEP § 1893.01:

¹ Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that [i]n the case of an international application, the phrase 'actual filing date of the application in the United States' [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371 (b) or (f)."

Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(1) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c).

MPEP § 1893.01. (emphasis added)

Thus, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.

B. Proper calculation of "B Delay" for the eventual patent based on the present application.

The present application is a § 371 national stage filing of International Application No. PCT/GB2004/003492, filed August 13, 2004, which claims priority benefit of Great Britain Application No. 0328690.3, filed December 10, 2003, and U.S. Provisional Application No. 60/554,990, filed March 19, 2004.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), 30 months from the priority date of the international application,² on June 10, 2006 (30 months from the priority date of December 10, 2003).

The period beginning on June 11, 2009 (the day after the date that is three years after June 10, 2006, the date that the national stage commenced), and ending the date the eventual patent issues should be credited to the Applicant as "B Delay". That period is 61 days as of the due date for the issue fee and would be in excess of 150 days if one uses as a reference the 6.5 months from allowance date used by the PTO for estimating PTA at the time of allowance.

² No request for early processing under 35 U.S.C. § 371(f) was filed for the present application.

The PTO's calculation of PTA made no provision for this "B Delay" and thus is plainly incorrect. The correct measure of "B Delay" by the PTO is measured from June 11, 2009, until the issue date, inclusive. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

IV. OVERLAP OF "A DELAY" AND "B DELAY"

As detailed in the PTO's calculations, "A Delay" accumulated during the following period: February 20, 2007, to May 23, 2008.

As detailed above, "B Delay" accumulated after June 10, 2009, until the eventual issue date.

Thus, the "A Delay" and the "B Delay" do not overlap (i.e., occur on the same calendar day. See *Wyeth v. Dudas*, (D.DC, CA No. 07-1492, Mem. Op. September 30, 2008), copy appended hereto.

V. APPLICANT DELAY

Applicants do not dispute, for purposes of this request, the PTO's calculation of time constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704. (24 days due to extension of time, November 29 to December 23, 2008). (See PTO's calculation.)

VI. TERMINAL DISCLAIMER

This patent is not subject to a terminal disclaimer.

VII. CONCLUSION – CORRECT PATENT TERM ADJUSTMENT

Because the PTO failed to calculate, or miscalculated "B Delay," the PTO's PTA calculation of 9 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

- 1) total PTO Delay should be calculated as the sum of "A Delay" (33 days) and "B Delay" (measured from June 11, 2009, to the issue date);
- 2) total Applicant Delay should be calculated as 24 days; and
- 3) total PTA should be calculated as 33 + "B Delay" – 24.

The fee of \$200.00 required under 37 C.F.R § 1.18(e) has been paid by credit card. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed, or which should have been filed herewith to our Deposit Account No. 13-2855, under Order No. 31265/5868A.

Dated: August 6, 2009

Respectfully submitted,

By: /David A. Gass #38,153/

David A. Gass

Registration No.: 38,153

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10/582,316

TUMOUR SUPPRESSOR PROTEIN

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Patent Term Adjustment

Filing or 371(c) Date:	02-20-2007	USPTO Delay (PTO) Delay (days):	33
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	24
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	9
USPTO Adjustment (days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
05-08-2009	Mail Notice of Allowance		
05-07-2009	Document Verification		
05-05-2009	Notice of Allowance Data Verification Completed		
05-05-2009	Case Docketed to Examiner in GAU		
05-05-2009	Examiner's Amendment Communication		
04-28-2009	Examiner Interview Summary Record (PTOL - 413)		
04-27-2009	Oath or Declaration Filed (Including Supplemental)		
03-11-2009	Mail Final Rejection (PTOL - 326)		
03-10-2009	Final Rejection		
01-15-2009	Date Forwarded to Examiner		
12-23-2008	Response after Non-Final Action		24
12-23-2008	Request for Extension of Time - Granted		⬆
08-29-2008	Mail Non-Final Rejection		⬆
08-28-2008	Non-Final Rejection		
07-05-2008	Date Forwarded to Examiner		
06-23-2008	Response to Election / Restriction Filed		
05-23-2008	Mail Restriction Requirement	33	
05-22-2008	Requirement for Restriction / Election	⬆	
01-25-2008	Change in Power of Attorney (May Include Associate POA)	⬆	
01-22-2008	Correspondence Address Change	⬆	
10-30-2007	Case Docketed to Examiner in GAU	⬆	
06-07-2007	PG-Pub Issue Notification	⬆	
03-27-2007	Case Docketed to Examiner in GAU	⬆	
03-06-2007	IFW TSS Processing by Tech Center Complete	⬆	
02-20-2007	371 Completion Date	⬆	
03-02-2007	Application Dispatched from OIPE		
03-02-2007	Notice of DO/EO Acceptance Mailed		
02-20-2007	Additional Application Filing Fees		
02-20-2007	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic		

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :
 :
 Plaintiffs, :
 :
 v. : Civil Action No. 07-1492 (JR)
 :
 JON W. DUDAS, Under Secretary of :
 Commerce for Intellectual :
 Property and Director of U.S. :
 Patent and Trademark Office, :
 :
 Defendant. :

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a) (2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b) (1) (A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b) (1) (B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ See 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b)(1)(b)(i)-(iii), as are periods attributable to the applicant's own delay. See 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b) (2) (A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b) (3) (A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b) (2) (A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b) (2) (A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b) (2) (A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b) (2) (A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b) (1) (B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that - again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C.

§ 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 07-1492 (JR)
	:	
JON W. DUDAS, Under Secretary of	:	
Commerce for Intellectual	:	
Property and Director of U.S.	:	
Patent and Trademark Office,	:	
	:	
Defendant.	:	

ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON
United States District Judge